

REMARKS

Applicant hereby requests further consideration of the application in view of the comments that follow. This response is submitted in reply to the Final Office Action mailed December 4, 2006 ("the Action"). Claims 1-27 are pending and stand rejected in the application. Claims 28-31 are new. Applicant will address the rejections below.

I. Comments on Response to Applicant's Prior Arguments

In response to Applicant's prior arguments regarding the teachings of U.S. Patent No. 5,619,995 to Lobodzinski ("Lobodzinski"), the Action states that this reference expressly teaches, "what is conventional in the art, the use of cine loop review and cine loop adjustment based on heart rate" (Action, p. 2, para. 3). The Action cites col. 2, line 4 and col. 13, line 15 of Lobodzinski in support of this position.

Applicant agrees that the general use of cine loops is known. *See, e.g., Quantification of cardiac function by conventional and cine magnetic resonance imaging*. Sechtem U, Pflugfelder P, Higgins CB. *Cardiovasc Intervent Radiol*. 1987;10(6):365-73, as described in the background reference article attached to the Response submitted on August 2, 2006. However, Applicant respectfully submits that, in the past, the MRI cine loops for cardiac stress analysis were asynchronous, that is the MRI data for the cine loops was collected, then manipulated at a later time. At col. 2, line 4, Lobodzinski states nothing other than "most diagnostic imaging systems provide some sort of cine' loop review." Notably, Lobodzinski goes on to also state that, "they typically do not provide digital motion video recording, serial comparison, and display functions" (emphasis added).

Further, at col. 13, lines 11-15, Lobodzinski merely describes QRS timing in video signal annotation (not cine loop adjustment as alleged by the Action). Indeed, at the cited portion of the text, Lobodzinski describes the video stream synchronization process and states:

The system first measures an average cardiac period for a given video sequence prior to data acquisition. A number of frames in each cycle will then be calculated as number of frames equal heart

period divided by 33. Typically a sequence of video fields is grabbed from an interlaced video output analog signal 36 (as shown in FIG. 2). Each frame with its associated odd and even fields (11, 12, 21, 22, etc.) will be numbered, starting with the first acquired frame, which is the end-diastolic for stress echocardiography applications, and its temporal position within a cardiac cycle will be stored together with compressed video data to the mass storage device (FIG. 1).

(col. 13, line 11-25)(emphasis added).

Again, Applicant respectfully emphasizes the technical differences between video streams and MRI cine loops (as was also noted by Lobodzinski). MRI cine loops are defined by electronically combining image data from single frame images of the same respective view of the heart at various points in time of cardiac cycles. Further, Lobodzinski fails to teach or suggest providing synchronized, adjusted MRI cine loops that are displayed in substantially real-time, much less while a patient is in an MRI scanner (*see, e.g.*, page 12, Figure 5 of the pending application). Claim 1 is restated here for ease of discussion.

1. A method of cardiac diagnostics of a patient, comprising:
 - administering a stress test to the patient;
 - acquiring a plurality of different views of MRI cine-loops of the heart of the patient at a plurality of heart rates the different views comprising some views associated with a first anatomical view at different heart rates induced by different doses of a stress-inducing substance and some views associated with different anatomical views at a substantially constant heart rate;
 - temporally synchronizing the plurality of MRI cine loops;
 - adjusting the plurality of temporally synchronized MRI cine loops based on a heart rate associated with respective ones of the MRI cines so as to compensate for differences in heart rate so that each MRI cine loop has substantially the same duration;
 - displaying a plurality of the adjusted MRI cine loops at a clinician workstation in substantially real-time while the patient is in an MRI scanner used for the acquiring step;
 - allowing a clinician to electronically select at least one of the following: (a) at least one dose amount; (b) at least one view; or (c) at least one dose amount and at least one view to define the MRI cine loops for the displaying step; and
 - evaluating the compensated MRI cine loops so as to assess a state of coronary physiology of the patient.

Applicant respectfully submits that Lobodzinski fails to teach or suggest at least the emphasized features. In further contrast, Applicant submits that embodiments of the invention can be used to monitor wall motion to appreciate early evidence of inducible ischemia, which is unique to MRI.

Regarding claims 21, 22 and 24, at para. 6, the Action also states that Lobodzinski teaches the adjustment of a viewing parameter or characteristic on one frame to be automatically transmitted to other frames, citing col. 12, lines 18-42 or col. 12, lines 60-65 and Figure 6. Applicant respectfully disagrees. These text passages refer to a drag and drop operation or automatically adjusting the display area -- which sizes the different video streams and describes that some video streams can have a different frame rate and/or a different size than display windows of other video streams.

Applicant respectfully submits that the cited reference fails to anticipate the subject matter of Claims 21, 22 or 24. As noted in the pending application, embodiments of the instant invention allow a clinician to rapidly adjust the display of the cine loop images by adjusting a feature in one frame that is propagated to other frames, thus not requiring each loop or frame be individually adjusted. The feature(s) can include, such as, for example, cropping to show only a portion of the original image, contrast, brightness, gamma or other display features, without adjusting each loop individually. Claim 22 recites that the frame is adjusted not only in the MRI cine loop with the user-adjusted frame but in other MRI cine loops as well, while there are a plurality of cine loops displayed. Claim 24 recites that the characteristic is a visual display level (opacity, brightness, contrast, etc.).

II. The Provisional Double Patenting Rejection

The Action rejects Claims 1, 3-4 and 6-18 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-13 of co-pending US Application Serial No. 10/628,915. The Action concedes that the "conflicting" claims are not

identical states that the claims are "not patentably distinct from each other because the current claims are broader in scope and are therefore anticipated by the conflicting claims" because they are not specific to wall motion cine loops and perfusion cine loops.

Applicant respectfully submits that the clarifying claim amendments made hereinabove obviate this rejection. However, should the Examiner maintain the rejection, Applicant reserves the right to submit a Terminal Disclaimer or amend the claims to overcome this rejection in this or the other co-pending application.

III. The 102(b) Rejection

The Action rejects Claims 1-7, 8-10, 12-19, 21, 22, 24, 26 and 27 as being anticipated by Lobodzinski. The Action rejects the other claims as being obvious over Lobodzinski in view of certain secondary references. Applicant again respectfully disagrees.

The Action concedes that much of the Lobodzinski disclosure is directed to ultrasound, but then states that Lobodzinski notes that other systems such as "cardiac Magnetic Resonance Imaging apparatus (col. 8, lines 10)" may also be used. (Action, p. 3).

As noted above, Applicant respectfully submits that Lobodzinski is directed to "video" streams signals rather than MRI cine loops. Lobodzinski discusses various prior art methods such as X-ray angiography (col. 2, lines 37) and characterizes them as being different, because they use only selected still images (col. 2, lines 40-45) and do not utilize real-time video compression. Lobodzinski also states that its proposed methods are distinctively different from the described methods of stress echocardiography (col. 5, lines 15-18). Thus, Lobodzinski itself stresses the technical differences from video versus still images used for cine, such as those used with MRI cine loops (see col. 2, lines 34-45, and col. 5, lines 10-25).

The instant invention does not employ a real-time video signal coming from the MR scanner, but rather employs separate images or "digital snapshots" of the heart taken at various times. As Lobodzinski states with respect to technologies that use still images, Applicant submits that the reverse is also true: the instant invention is "distinctively different" from the real-time stream of video proposed by Lobodzinski. MRI builds up a collection of

snapshots of the heart at various points in the cardiac cycle, but these snapshots require many heartbeats to acquire, and, hence, are simply representative of typical images of the heart averaged over those many heartbeats. Further, there is only one set of frames spanning the one 'representative' heart cycle. In a video stream, there is a real-time stream of many heartbeats.

Claim 1 recites:

1. A method of cardiac diagnostics of a patient, comprising:
 - administering a stress test to the patient;
 - acquiring a plurality of different views of MRI cine-loops of the heart of the patient at a plurality of heart rates the different views comprising some views associated with a first anatomical view at different heart rates induced by different doses of a stress-inducing substance and some views associated with different anatomical views at a substantially constant heart rate;
 - temporally synchronizing the plurality of MRI cine loops;
 - adjusting the plurality of temporally synchronized MRI cine loops based on a heart rate associated with respective ones of the MRI cines so as to compensate for differences in heart rate so that each MRI cine loop has substantially the same duration;
 - displaying a plurality of the adjusted MRI cine loops at a clinician workstation in substantially real-time while the patient is in an MRI scanner used for the acquiring step;
 - allowing a clinician to electronically select at least one of the following: (a) at least one dose amount; (b) at least one view; or (c) at least one dose amount and at least one view to define the MRI cine loops for the displaying step; and
 - evaluating the compensated MRI cine loops so as to assess a state of coronary physiology of the patient.

Applicant respectfully submits that the above-noted claims are not anticipated by the cited reference for at least failing to teach the emphasized features and respectfully request that this rejection be withdrawn.

IV. The Obviousness Rejections

Applicant respectfully submits that the dependent claims are allowable for depending from a patentable base claim. Applicant also submits that the dependent claims are also patentable for the recitation of separately patentable subject matter.

Claim 20

The Action concedes that the primary reference fails to teach registration but cites U.S. 6,500,123 to Holloway ("Holloway") as teaching this feature. Applicant submits that, in contrast to Holloway which registers 1st and 2nd ultrasound datasets, the method recites registering frames of the plurality of MRI cine loops to the baseline MRI cine loop.

Claim 23

The Action concedes that the primary reference fails to teach cropping frames to provide a portion of the frame, but opines that U.S. Patent No. 5,680,862 to Song et al. (Song) does so. Thus, the Action alleges that one of skill in the art would have found it obvious to modify Lobodzinski to use cropping.

At the cited passage, Song describes cropping an original image of 256x256 to a 64x64 region, but does so with respect to algorithms for determining the trajectory of a particle in motion based on allegedly an optimal computerized iteration method (Abstract). Song does not describe allowing user input to determine a crop region, then propagating the selected crop to other images in the cine loop, much less to the other displayed cine loops.

In contrast with Song, embodiments of the invention are directed to automatic propagation of a viewing parameter, using clinician input so as to allow a clinician to focus on a region of interest and cropping one frame, the subsequent images in the cine loop(s) then being automatically adjusted with the same selected crop detail. Thus, even combined, Song fails to remedy the deficiencies of Lobodzinski. That is, properly combined, the video loops of Lobodzinski would incorporate an optimized iterative method of determining trajectory of a moving region.

Applicant respectfully submits that Claim 23 is allowable over the cited art.

Claim 25

The Action rejects Claim 25 as being obvious over the primary reference in view of U.S. 2002/0077538 To Saranathan ("Saranathan"). The Action concedes that Lobodzinski fails to include the details of the fast-gradient echo segmented k-space sequence but alleges that Saranathan teaches an MRI cine display with a temporal resolution between 13 and 65 ms (citing paragraphs 39 and 43). Applicant respectfully disagrees. Indeed, Saranathan is directed to "free-breathing" MR images. Also, this reference states that "MR fluoroscopy can be treated as a special case" with $n=1$, resulting in a 66 ms temporal resolution. In contrast, MR fluoroscopy is not required for the temporal resolutions provided by the recitation of Claim 25.

25. A method according to Claim 1, further comprising obtaining MRI images for the MRI cine loops using a fast gradient echo segmented k-space sequence having sufficient temporal resolution for identification of end of systole without MR fluoroscopy, the temporal resolution being between about 13-65 ms, with lower times corresponding to faster heart beats and higher times corresponding to slower heartbeats, and wherein the MRI cine loops are obtained using breathhold durations between about 10-23 seconds, the longer breathhold durations associated with faster heart beat rates.

Applicant respectfully submits that Claim 25 is patentable over the cited references.

Claim 27

Applicant also submits that Claim 27 is patentable over the cited art, as the cited art fails to teach or suggest storing the defined viewing adjustment and subsequently automatically displaying the cine loops with the defined adjustment at a later time.

V. The New Claims

Applicant has added new Claims 28-31 above to form a more complete claim set for the application. Applicant submits that the claims are supported by the application. Entry and consideration of the claims is requested.

VI. Supplemental Information Disclosure Statement ("IDS")

Applicant is submitting a Supplemental IDS listing the reference that the Examiner stated was not submitted in a prior IDS (Sechtem et al.) as well as two Rule 132 Declarations of pre-patent Filing Activities Summaries by Dr. Hamilton, one of the co-inventors, and listing other documents. Although Applicant believes that the Sechtem et al. reference was submitted, a duplicate copy is enclosed with this response. Applicant requests that the Examiner return an initialed copy of the listing indicating that the Supplemental IDS was considered for the record.

CONCLUSION

Accordingly, Applicant submits that the present application is in condition for allowance and the same is earnestly solicited. Should the Examiner have any matters outstanding of resolution, she is encouraged to telephone the undersigned at 919-854-1400 for expeditious handling.

Respectfully submitted, ~



Julie H. Richardson

Registration No.: 40,142

USPTO Customer No. 20792
Myers Bigel Sibley & Sajovec
Post Office Box 37428
Raleigh, North Carolina 27627
Telephone: 919/854-1400
Facsimile: 919/854-1401

CERTIFICATION OF TRANSMISSION UNDER 37 CFR § 1.8

I hereby certify that this correspondence is being transmitted electronically to the U.S. Patent and Trademark Office on March 14, 2007.


Rosa Lee Brinson